

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 14 August 2000 (14.08.00)	
International application No. PCT/JP99/07165	Applicant's or agent's file reference G951-PCT
International filing date (day/month/year) 21 December 1999 (21.12.99)	Priority date (day/month/year) 21 December 1998 (21.12.98)
Applicant MORIYAMA, Naohiko et al	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

15 July 2000 (15.07.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Kiwa Mpay

Telephone No.: (41-22) 338.83.38

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference G951-PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/JP 99/ 07165	International filing date (day/month/year) 21/12/1999	(Earliest) Priority Date (day/month/year) 21/12/1998
Applicant TEIJIN LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (see Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP 99/07165

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple(groups of) inventions in this international application, as follows:

1. Claims: 1-13,19
Apparatus for preparing a fluid for medical procedure
2. Claims: 14-18
Cutter for partially cutting a membrane along a periphery of an opening of a vessel

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/JP 99/07165

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61J B67B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 788 099 A (TREU ET AL.) 4 August 1998 (1998-08-04) column 4, line 7 -column 6, line 37 figures 1-5	1-3, 5, 10, 11, 13, 14, 19
Y		6-9, 15-18
X	US 4 197 942 A (GACKI ET AL.) 15 April 1980 (1980-04-15) figures 1B, 3A, 4A, 4B column 10, line 35 -column 11, line 15	14 1, 10, 19
A		
Y	US 5 366 114 A (BERNSTEIN ET AL.) 22 November 1994 (1994-11-22) abstract figures 2-5	6-9, 15-18



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

30 March 2000

Date of mailing of the international search report

06/04/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3018

Authorized officer

Schönleben, J

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/JP 99/07165

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5788099	A	04-08-1998	US 5591344 A	07-01-1997
			AU 698545 B	29-10-1998
			AU 4444996 A	22-08-1996
			AU 4977996 A	04-09-1996
			CA 2168629 A	14-08-1996
			DE 19605260 A	28-11-1996
			GB 2299026 A,B	25-09-1996
			GB 2310613 A,B	03-09-1997
			GB 2310614 A	03-09-1997
			GB 2310615 A,B	03-09-1997
			GB 2310602 A,B	03-09-1997
			GB 2310616 A,B	03-09-1997
			GB 2310617 A,B	03-09-1997
			GB 2310618 A,B	03-09-1997
			GB 2320210 A,B	17-06-1998
			GB 2320209 A,B	17-06-1998
			JP 9000618 A	07-01-1997
			WO 9625214 A	22-08-1996
			US 5674404 A	07-10-1997
			US 5705066 A	06-01-1998
			US 5645734 A	08-07-1997
			US 5690831 A	25-11-1997
			US 5658456 A	19-08-1997
			US 5707086 A	13-01-1998
			US 5674397 A	07-10-1997
			US 5630935 A	20-05-1997
			US 5690821 A	25-11-1997
			US 5725776 A	10-03-1998
			US 5670050 A	23-09-1997
			US 5702606 A	30-12-1997
			US 5674390 A	07-10-1997
			US 5651893 A	29-07-1997
			US 5714060 A	03-02-1998
			US 5932110 A	03-08-1999
			US 5788851 A	04-08-1998
			US 5783072 A	21-07-1998
			US 5716531 A	10-02-1998
			US 5762782 A	09-06-1998
			US 5863421 A	26-01-1999
			US 5932103 A	03-08-1999
US 4197942	A	15-04-1980	US 4103358 A	25-07-1978
			CA 1106218 A	04-08-1981
			CA 1102163 A	02-06-1981
			CA 1124563 A	01-06-1982
			CA 1126563 A	29-06-1982
			CA 1166183 A	24-04-1984
			US RE30610 E	12-05-1981
			US 4217054 A,B	12-08-1980
US 5366114	A	22-11-1994	US 5297696 A	29-03-1994

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Ishida, Takashi.
A. AOKI, ISHIDA, & ASSOCIATES
Toranomom 37 Mori Bldg., 5-1,
Toranomom 3-chome, Minato-Ku
TOKYO 105-8423
JAPON



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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year) 17.01.2001

Applicant's or agent's file reference
G951-PCT

IMPORTANT NOTIFICATION

International application No.
PCT/JP99/07165

International filing date (day/month/year)
21/12/1999

Priority date (day/month/year)
21/12/1998

Applicant
TEIJIN LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized officer

Dekker, M

Tel.+31 70 340-4046



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference G951-PCT	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP99/07165	International filing date (<i>day/month/year</i>) 21/12/1999	Priority date (<i>day/month/year</i>) 21/12/1998	
International Patent Classification (IPC) or national classification and IPC A61M1/16			
Applicant TEIJIN LIMITED et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 7 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 15/07/2000	Date of completion of this report 17.01.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Schönleben, J Telephone No. +31 70 340 2436 <div style="text-align: right;">  </div>

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP99/07165

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:

Description, pages:

1-15 as originally filed

Claims, No.:

1-19 as originally filed

Drawings, sheets:

1/13-13/13 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP99/07165

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-13,15-19
	No: Claims 14
Inventive step (IS)	Yes: Claims
	No: Claims 1-19

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/JP99/07165

Industrial applicability (IA) Yes: Claims 1-19
 No: Claims

2. Citations and explanations
 see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Re Item IV

Lack of unity of invention

Claims 1 to 9, 10 to 13 and 19 are related to an apparatus for preparing a fluid for a medical procedure. The object to be solved by these claims is to provide an apparatus which allows mixing of at least one medicament in the form of powder with water. Claims 14 to 18 are related to a cutter for partially cutting a membrane along a periphery of an opening of a vessel. The object to be solved by these claims is to provide a cutter which avoids a complete cutting of the membrane. Thus, the subject-matters of these two groups of claims are different and none of the independent claims of these two groups comprises same or corresponding special technical features, so that a technical relationship in the meaning of Rule 13.1 of the PCT does not exist between these claims. Without a technical relationship the different subject-matters are not so linked as to form a single inventive concept.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. US-A-5788099 discloses an apparatus for preparing a fluid for a medical procedure by mixing of at least one medicament in the form of a powder with water, the medicament being held in a vessel 250 which defines a bottom, a side wall, and a top opening which is closed by a membrane 222 for sealing the inside of the vessel, the apparatus comprising a source of water 120, an opener 368 for opening the membrane of the vessel, the opener including a holder 220, 334 for vertically holding the vessel to downwardly orient the opening, a cutter 242, 146, provided beneath the opening of the vessel held by the holder, for partially cutting the membrane along the periphery of the opening, a mechanism 340 for vertically moving the holder and the cutter relative to one another so that the cutting edge 146 of the cutter 242 pierces and partially separates (see fig. 5c) the membrane 222 from the periphery of the opening whereby the medicament in the vessel falls from the vessel, a receiving member 134 provided beneath the cutter for receiving all of the medicament from the vessel, and a nozzle 142 for directing water from the source 120 of water in the form of a spray to the medicament received by the receiving member 134 to dissolve the medicament into the

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/JP99/07165

water directed to the medicament, and a tank 108 for receiving and containing the substances dissolved in the sprayed water.

The subject-matter of claim 1 differs from this state of the art only in that the moving mechanism is moving the holder towards the cutter and that the receiving member is in the form of a mesh.

This differences, however, cannot be considered as involving an inventive step (Article 33(3) PCT) insofar as they comprise only slight constructional changes which come within the scope of customary practice followed by persons skilled in the art and can be interchanged with each other where circumstances make it desirable. For example, if the container receiving and containing the substances is arranged in line with the cutter and not next to the cutter, then it is obvious that the receiving member has to be in the form of a mesh in order to allow transferring of the mixed substances to the tank. Additionally, whether the cutter is moving toward the holder or the holder toward the cutter is just an equivalent, which cannot support an inventive step.

2. The same objection as above is relevant to claims 10 and 19. Claim 10 is related to an opener, which comprises all the features of claim 1 except the source of water and the tank for receiving and containing the substance dissolved in the sprayed water. Claim 19 is related to an apparatus for preparing a fluid for a medical procedure as in claim 1 comprising instead of one vessel and one opener two vessels and two openers. Such an arrangement is, however, also disclosed in US-A-5788099 (see e.g. col. 5, lines 30 to 36).

3. Independent claim 14 is related to a cutter for partially cutting a membrane along a periphery of an opening of a vessel. The cutter disclosed in US-A-5788099 also discloses all the features of this claim: A cutter body substantially in the form of a hollow cylinder having an inclined end (see col. 5, lines 55 to 63, and fig. 5a-5c), a cutting edge 146 provided along the inclined end, and a slit extending from the inclined end into the cutter body (see e.g. fig. 5a and c).

Thus, the subject-matter of claim 14 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3)) PCT) so that this claim does not meet the criterion set forth in Article 33(2) PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/JP99/07165

Additionally, US-A-4197942 also discloses a cutter comprising all the features of claim 14 (see this document col. 10, lines 35 to col. 11, line 15, and fig. 4a, 4b).

4. Dependent claims 2 to 9, 11 to 13, and 15 to 18 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step. See for example:

US-A-5788099, fig. 1, 2 and 4, for claims 2, 3, 5 11 and 13;

US-A-5366114, abstract and fig. 2 to 5, for claims 6 to 9 and 15 to 18.

) Claims 4 and 12 related to the mesh size specify just parameters which easily can be defined by a skilled person knowing the medicaments to be dissolved.

Re Item VII

Certain defects in the international application

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

) Independent claims 1, 10, and 14 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document US-A-5788099, see also item V above) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

Claim 19 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

The relevant background art disclosed in US-A-5788099 has not been mentioned and identified in the description.

CK

PATENT COOPERATION TREATY

WO 00/37127
PCT/JP99/07165

PCT

NOTICE INFORMING THE APPLICANT OF THE
COMMUNICATION OF THE INTERNATIONAL
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

ISHIDA, Takashi
A. Aoki, Ishida & Associates
Toranomon 37 Mori Building
5-1, Toranomon 3-chome
Minato-ku
Tokyo 105-8423
JAPON

157



Date of mailing (day/month/year) 29 June 2000 (29.06.00)		
Applicant's or agent's file reference G951-PCT		IMPORTANT NOTICE
International application No. PCT/JP99/07165	International filing date (day/month/year) 21 December 1999 (21.12.99)	Priority date (day/month/year) 21 December 1998 (21.12.98)
Applicant TEIJIN LIMITED et al		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
AU,CN,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,GE,
GH,GM,HR,HU,ID,IL,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,NO,NZ,
OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
29 June 2000 (29.06.00) under No. WO 00/37127

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

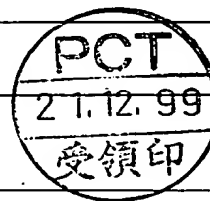
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer J. Zahra Telephone No. (41-22) 338.83.38
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PCT REQUEST

G951-PCT

Original (for SUBMISSION) - printed on 21.12.1999 04:24:55 PM

0	For receiving Office use only	
0-1	International Application No.	
0-2	International Filing Date	
0-3	Name of receiving Office and "PCT International Application"	
0-4	Form - PCT/RO/101 PCT Request Prepared using	PCT-EASY Version 2.90 (updated 15.10.1999)
0-5	Petition The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	Receiving Office (specified by the applicant)	Japanese Patent Office (RO/JP)
0-7	Applicant's or agent's file reference	G951-PCT
I	Title of invention	AN APPARATUS FOR PREPARING A FLUID FOR A MEDICAL PROCEDURE
II	Applicant	applicant only
II-1	This person is:	all designated States except US
II-2	Applicant for	TEIJIN LIMITED
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IV-2	Additional agent(s)	additional agent(s) with same address as first named agent
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V	Designation of States	
V-1	Regional Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	<p>AP: GH GM KE LS MW SD SL SZ TZ UG ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT</p> <p>EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT</p> <p>EP: AT BE CH&LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE and any other State which is a Contracting State of the European Patent Convention and of the PCT</p> <p>OA: BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT</p>
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V-5	Precautionary Designation Statement In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.	
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VI-1-2	Number	Patent Application 10-362828
VI-1-3	Country	JP

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VII-1	International Searching Authority Chosen	European Patent Office (EPO) (ISA/EP)	
VIII	Check list	number of sheets	electronic file(s) attached
VIII-1	Request	5	-
VIII-2	Description	15	-
VIII-3	Claims	6	-
VIII-4	Abstract	1	g951.txt
VIII-5	Drawings	13	-
VIII-7	TOTAL	40	
	Accompanying items	paper document(s) attached	electronic file(s) attached
VIII-8	Fee calculation sheet	✓	-
VIII-9	Separate signed power of attorney	✓	-
VIII-16	PCT-EASY diskette	-	diskette
VIII-17	Other (specified):	patent revenue stamps	-
VIII-18	Figure of the drawings which should accompany the abstract	1	
VIII-19	Language of filing of the International application	English	
IX-1	Signature of applicant or agent	<i>Takashi Ishida</i>	
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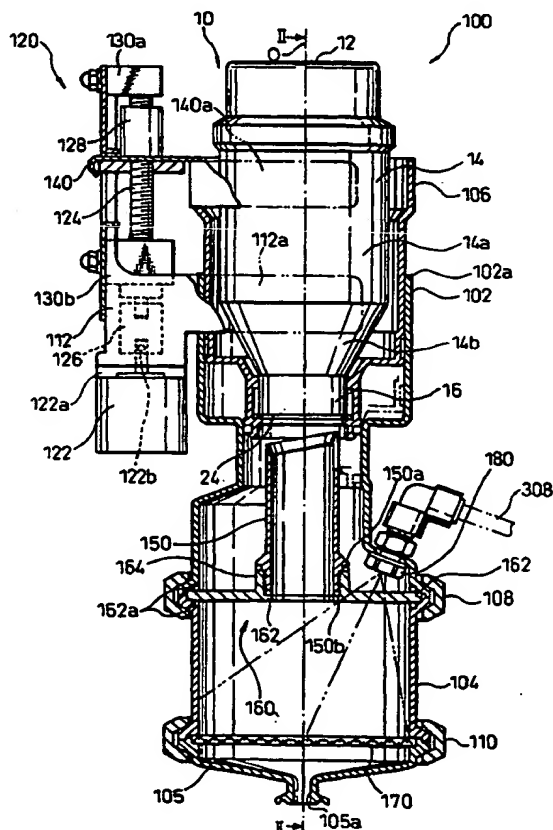
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(54) Title: AN APPARATUS FOR PREPARING A FLUID FOR A MEDICAL PROCEDURE

(57) Abstract

The invention provides an apparatus for preparing a fluid for a medical procedure by mixing of at least one medicament in the form of powder with water, the medicament is held in a vessel which defines a bottom, a side wall, and a top opening which is closed by a membrane for sealing the inside of the vessel. The apparatus includes an opener for opening the membrane of the vessel. The opener includes a holder for vertically holding the vessel to downwardly orient the opening; a cutter, provided beneath the opening of the vessel held by the holder, for partially cutting the membrane along the periphery of the opening; a mechanism for vertically moving the holder toward the cutter so that the cutting edge of the cutter pierces to partially separate the membrane from the periphery of the opening whereby the medicament in the vessel falls from the vessel; a receiving member, in the form of a mesh provided beneath the cutter, for receiving all of the medicament from the vessel; and a nozzle for directing water from the source of water in the form of a spray to the medicament received by the receiving member to dissolve the medicament into the water directed to the medicament.



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DESCRIPTION

AN APPARATUS FOR PREPARING A FLUID
FOR A MEDICAL PROCEDURE

5

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to an apparatus for preparing a fluid for a medical procedure, an opener for unsealing a vessel containing a medicament, and a cutter for the opener.

2. Description of the Related Art

Recently, an apparatus for preparing a fluid for a medical procedure, such as dialysis treatment, has been proposed. The fluids for dialysis treatment includes an acetic acid aqueous solution, which is prepared by diluting an acetic acid stock solution with water, in particular reverse osmosis water (referred to RO water in this specification), and a sodium bicarbonate aqueous solution, which is prepared by dissolving sodium bicarbonate powder in RO water.

Japanese Patent Publication (Kokai) No. 5-168678 (JPP '678) describes an apparatus for preparing sodium bicarbona aqueous solution. The apparatus holds an inverted vessel for containing a solid medicament, sodium bicarbona, in the form of a powder or granules, after the vessel is unsealed, so that the contents fall by gravity into a tank which contains water. The tank includes an agitator for promoting the mixing of the medicament with the water. The apparatus of JPP '678 has a problem that the sodium bicarbona, which has been fallen into the tank, cannot be solved quickly in the water within the tank since the dissolid medicament deposits on the bottom of the tank.

Japanese Patent Publication (Kokai) No. 4-84967 (JPP '967) also describes an apparatus for preparing sodium

bicarbona aqueous solution. The apparatus is configured to dissolve and wash out sodium bicarbonate contained within a vessel by spraying water into the inverted vessel after the vessel is unsealed. However, with the apparatus of JPP '967, dissolving the solid content within the vessel cannot be sufficiently carried out due the small volume available for the dissolving process so that the substantial portion of the sodium bicarbona is wash out of the vessel without dissolving into the water sprayed into the vessel.

SUMMARY OF THE INVENTION

The invention is directed to solve the prior art problems, and to provide an improved apparatus for preparing a fluid for a medical procedure.

Further, the objective of the invention is to provide an opener for unsealing a vessel containing a medicament used for preparing the fluid for a medical procedure

Further, the objective of the invention is to provide a cutter for the opener.

The invention provides an apparatus for preparing a fluid for a medical procedure by mixing of at least one medicament in the form of powder with water, the medicament is held in a vessel which defines a bottom, a side wall, and a top opening which is closed by an membrane for sealing the inside of the vessel. The apparatus includes a source of water for dissolving the medicament. An opener is provided for opening the membrane of the vessel. The opener includes a holder for vertically holding the vessel to downwardly orient the opening; a cutter, provided beneath the opening of the vessel held by the holder, for partially cutting the membrane along the periphery of the opening; a mechanism for vertically moving the holder toward the cutter so that the cutting edge of the cutter pierces to partially separate the membrane from the periphery of the opening

whereby the medicament in the vessel falls from the vessel; a receiving member, in the form of a mesh provided beneath the cutter, for receiving all of the medicament from the vessel; and a nozzle for directing water from the source of water in the form of a spray to the medicament received by the receiving member to dissolve the medicament into the water directed onto the medicament. A tank is provided for receiving and containing the substances dissolved into the sprayed water.

According to one feature of the invention, the tank is adapted to receive the water from the water source. The apparatus further includes a circulating system for supplying the water from the tank to the nozzle.

According to another feature of the invention, the opener may include a housing for enclosing the cutter and the receiving member. The holder is vertically displaceable relative to the housing; and the nozzle is attached to the housing to direct the water to the medicament received by the receiving member from outside of the housing.

According to another feature of the invention, the mechanism includes a feed screw vertically supported for rotation; a motor, connected to one end of the feed screw, for rotating the screw; a nut engaging the feed screw; and a member connected between the nut and the holder.

According to another feature of the invention, the cutting edge includes a serrated portion provided along the inclined end. The serrated portion may be partially provided along the inclined end of the cutter body and, in particular, disposed on the proximal half of the inclined end. The serrated portion may be provided all around the inclined end of the cutter body.

DESCRIPTION OF THE DRAWINGS

These and other objects and advantages and further

description will now be discussed in connection with the drawings in which:

Figure 1 is a vertical section of an embodiment of an opener according the invention;

5 Figure 2 is a vertical section of the opener along line I - I in Figure 1;

Figure 3 is a vertical section of a holder according to the embodiment shown in Figure 1;

10 Figure 4 is a partially enlarged side view of a vessel according to the embodiment shown in Figure 1;

Figure 5A is a side view of a cutter according to the embodiment shown in Figure 1;

Figure 5B is another side view of the cutter in the direction VB - VB in Figure 5A;

15 Figure 5C is a horizontal section of the cutter along line VC - VC in Figure 5A;

Figure 5D is a partially enlarged section of the cutting edge of the cutter along line VD - VD in Figure 5E;

20 Figure 5E is a partially enlarge side view of the cutting edge of the cutter;

Figure 6 is a perspective view of a cutter according to another embodiment of the invention;

25 Figure 7 is a cutter support according the embodiment shown in Figure 1;

Figure 8 is a vertical section of an opener according to another embodiment of the invention;

Figure 9A is a side view of a cutter according to the embodiment shown in Figure 8;

30 Figure 9B is another side view of the cutter shown in Figure 9A;

Figure 9C is a plan view of the cutter viewed in the direction of IXC - IXC in Figure 1A;

35 Figure 10 is an opener according to another embodiment of the invention; and

Figure 11 is an apparatus for preparing a fluid for a medical procedure according to the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 11 shows an example of an apparatus for preparing a fluid for a medical procedure according an embodiment of the invention. The apparatus 300 includes a tank 302 for containing the fluid, first and second openers 100 and 200 for opening bottles or first and second vessels 10 and 30 which contain medicament in the forms of powder and liquid, respectively. A pump 304 is provided for circulation of the liquid within the apparatus 300. RO water is supplied to the tank 302 from a RO water source 320 through a supply conduit 318. The RO water contained in the tank 302 is then supplied to the first opener 100 through a main conduit 306 including the pump 304 and a branch conduit 308 connected between the main conduit 306 and the first opener 100. Likewise, the RO water is supplied to the second opener 200 through the main conduit 306 and a branch conduit 314 connected between the main conduit 306 and the second opener 200.

The first opener 100 opens the seal of the first vessel 10 to remove the medicament in the form of powder from the first vessel 10 and receives it. The medicament received by the first opener 100 is dissolved into the OR water supplied to the first opener 100. The liquid containing the dissolved medicament flows back to the tank 302 through a return conduit 312.

Likewise, the second opener 200 opens the seal of the second vessel 30 to remove the medicament in the form of liquid from the second vessel 30. The medicament from the second vessel 30 is mixed with the OR water supplied to the second opener 100, and the mixture flows back to the tank 302 through a return conduit 316.

With reference to Figures 1 - 7, the first opener 100 according to the embodiment of the invention will be described below.

The first opener 100 includes a housing defined by upper and lower housings 102 and 104 and a bottom 105

which are connected to each other by a clamp rings 108 and 110. The upper housing 102 defines an upper open end 102a for receiving a holder 106. The holder 106 is
5 displaceable relative to and within the upper housing 102 in the vertical direction along the central axis "O" of the housing. The bottom 105 has an outlet 105a which is adapted for the connection with the conduit 312.

With reference to Figure 3, the holder 106 has a substantially cylindrical side wall 118 defining an upper
10 open end 106a for receiving a first vessel 10, as described hereinafter, and a neck 114 defining a lower opening end 106b. The neck 114 further defines a plurality of inwardly extending lugs 116 which are equally disposed at its upper end and an inwardly
15 extending annular stop 114a adjacent to its lower end. The side wall 118 may have a plurality of inclined ribs 118a for aiding the insertion of the first vessel 10.

The first vessel 10 is adapted to contain solid medicament in the form of power or granular and has a
20 bottom 12, a side wall 14 and a neck 16 which has a radius smaller than the side wall 14. The side wall 14 includes a cylindrical portion 14a and a truncated cone portion 14b which connects the end of the upper cylindrical portion 14a opposite to the bottom 12 to one
25 end of the neck 16.

With reference to Figure 4, the neck 16 includes a plurality of engagement portions 20 and screw portions 22. Each of the engagement portions includes a guide
30 portion spirally extending along the outer surface of the neck 16, a stop portion 20b provided upper end of the spirally extending guide portion 20a and a protrusion 20c. The neck 16 further defines an opening 18 which is air-tightly sealed by a seal in the form of a membrane 24. Though the opening 18, a solid medicament in the
35 form powder or granules is charged into and removed from the first vessel 10.

The engagement portions 20 are equally disposed on

the outer surface of the neck 16 about the axis 02 of the first vessel 10 so that space 16a is provided between the stop 20b and the end of the guide 20a of the adjacent engagement portion 20. Likewise, the screw portions 22
5 are disposed on the outer surface of the neck 16 to provide the spaces 16a between the adjacent screws 22. The spaces 16a allow the passage of the protrusions 20c when the first vessel 10 is attached to the holder 112.

Figures 1 and 2 show the first opener 100 with the
10 first vessel 10 mounted thereto. The first opener 100 has a cutter 150 which is provided within the housing opposite to the opening 18 of the first vessel 10.

The upper housing 102 of the first opener 100 is vertically supported by a stationary frame 112. The
15 frame 112 has a pair of arms 112a which extend horizontally along the outer surface of the side wall upper housing 102 and are secured thereto by a plurality of screws 112b (Fig. 2).

The first opener 100 further includes a mechanism
20 120 for vertically moving the holder 106. The mechanism 120 includes an electric motor 122 attached to the frame 112 by a bracket 122a, and a vertically extending feed screw 124 supported by bearings 130a and 130b at the ends of the screw 124. At the lower end of the feed screw 124
25 is connected to the shaft 122b of the motor 122 by a coupling 126. A nut 128 which engages the feed screw 124 is mounted to a connection member 140. The connection member 140 has a pair of arms 140a which extend horizontally along the outer surface of the side wall of
30 the cutter support 160 and are secured thereto by a plurality of screws 140b (Fig. 2).

With reference to Figures 5A to 5E, the configuration of the cutter 150 is described below.

The cutter 150 includes a substantially cylindrical
35 cutter body 150 with a lower end defining a threaded portion 154, a flange 155 provided over the threaded portion 154, and an inclined upper end 156 defining an

cutting edge. The cutter body 152 further includes a plurality of openings 152a (four openings 152a are shown in this embodiment) which define columns 152b supporting the upper portion of the cutter body 152.

5 The upper end 156 inclines from a plane perpendicular to the axis of the cutter body 152 by an angle α (Fig. 5B) of, preferably, 15 - 30 degrees. From the peak of the inclined end 156, a slit 158 vertically extends to one of the opening 152a. The inclined end 156
10 includes a plain cutting edge portion 156a which extend along upper half of the inclined end 156 and a serrated edge portion 156b provided on the lower half of the inclined end 156. Figure 5D shows a portion of the serrated portion 156b, and Figure 5E shows a partial side
15 section of the serrated portion 156b along line VE - VE in Figure 5D. The pitch "P" (see Figure 5E), the distance between the peaks of the adjacent teeth of the serrated portion 156a, may be 1 - 5 mm, preferably 3 mm, and the depth "D" of the teeth may be 1 - 5 mm,
20 preferably 3 mm. Further, the attack angle β may be 15 - 30 degrees, preferably 20 degrees. Further, the serrated portion may be provided all around the inclined end of the cutter body as shown in Figure 6.

25 The cutter 150 is attached to and supported by an inner frame 160 which is clamped between the upper and lower housings 102 and 104. With reference to Figure 7, the inner frame 160 includes a circular base 162 adapted to be clamped by the housings 102 and 104 with seal rings 162a provided therebetween (Figs. 1 and 2), and a central
30 mount 164 which is connected to the circular base 162 by radial spokes 168. The central mount 164 has a substantially cylindrical shape with a central bore including a threaded inner surface and a stop 162. The
35 cutter 150 is attached to the central mount 164 through the engagement between the threaded portion 154 of the cutter 150 and the threaded inner surface of the central

mount 164 with O-rings 150a and 150b clamped therebetween (Figs. 1 and 2).

5 A receiving member 170, for receiving the solid medicament falling down from the first vessel 10 when the seal is broken by the first opener 100, is provided between the lower housing 104 and the bottom 105. The receiving member 170 includes a screen which can receive the medicament from the first vessel 10. The size of the powder of granules of sodium bicarbonate of 200 μm is
10 generally used for preparing a fluid for dialysis treatment. Therefore, the mesh size of the screen is of at most 200 μm . On the other hand, a screen having a unnecessarily small mesh size, for example under 20 μm , inhibits the flow of the solution through the mesh, which
15 results in increase in the pressure within the housing above the screen to break the seal of the first opener 100. The typical mesh size for the screen is of at least 20 μm , preferably 50 - 150 μm .

20 A water supply nozzle 180 is mounted to the housing of the first opener 100 and connected to the branch conduit 308. The water supply nozzle 180 is oriented to the receiving member 170 to direct the water in the form of a spray onto the medicament received on the receiving member 170.

25 The first opener 100 further includes a pair of washing nozzles 182 and 184 connected to a branch conduit 310 which is further connected to the main conduit 306 (Fig. 11). The washing nozzles 182 and 184 are horizontally oppositely oriented to the cutter 150 to
30 direct the liquid from the tank 302 in the form of a spray for the purpose of washing inside of the housing of the first opener 100 and the cutter 150 after an operation of dissolving the medicament received on the receiving member 170 by spraying the RO water from the
35 water supplying nozzle 180.

With reference to Figures 8 - 9C, the second opener

200 will be described below.

The second opener 200 is configured substantially the same as the first opener 100, except that the second opener 200 is adapted to open the seal of the second
5 vessel 30 for containing a liquid medicament while the first opener 100 is adapted to open the first vessel 10 for containing a solid medicament in the form of power or granular.

The second opener 200 includes upper housing 202 and
10 lower housing 204 which are connected to each other by a clamp ring 208 to define the housing of the second opener 200. The lower housing defines a bottom of the housing and an outlet 204a for connection with the return conduit 316 (Fig. 11).

15 The upper housing 202 vertically displaceably receives a holder 206 for holding the second vessel 30. A mechanism 220, which is configured substantially the same as the mechanism 120 of the first opener 100, is provided for vertically moving the holder 206 relative to
20 the upper housing 202.

A cutter 250 is provided within the housing opposite to the opening of the first vessel 30. The cutter 250 is formed substantially the same as the cutter 150 of the
25 first opener 100, except that the cutter 250 of the second opener 200 is formed into one piece while the cutter 150 of the first opener 100 includes two pieces. The cutter 250 includes substantially a cylindrical cutter body 252 and a circular base portion 254. The
30 cutter body 252 is disposed at the center of the circular base portion 254 and supported by radial spokes 260. The circular base portion 254 is adapted to be clamped by the housings 202 and 204 with seal rings provided therebetween (Figs. 1 and 2),

35 The cutter body 252 includes an inclined upper end 256 defining an cutting edge. The upper end 256 inclines from a plane perpendicular to the axis of the cutter body 252, the same as the cutter of the first opener 100.

From the peak of the inclined end 256, a slit 258 vertically extends into the cutter body 252. The inclined end 256 includes an plain cutting edge portion 256a which extend along upper half of the inclined end 256 and a serrated edge portion 256b provided on the lower half of the inclined end 256.

A water supplying nozzle 262 is attached to the bottom of the lower housing 204. The water supplying nozzle 262 is oriented substantially to the center of the cutter 250 to direct the water in the form of a spray to the inside of the second vessel 200 through the central bore of the cutter 250 for the purpose of flushing the inside of the second vessel.

The functional operation of the apparatus for preparing a fluid for a medical procedure of the invention will be described below.

First, the first and second vessels 10 and 30 are mounted to the first and second openers 100 and 200, respectively. The first and second vessels 10 and 30 are inverted after their caps (not shown) are removed. The necks 16 and 36 of the first and second vessels 10 and 30 are inserted into the bores defined by the necks 114 and 214 of the holders 106 and 206 of the first and second openers 100 and 200, respectively, so that the lugs 116 and 216 pass through the spaces 16a (only the space 16a of the first vessel 10 is shown in the drawings) provided on the outer surfaces of the necks 16 and 36. When the ends of the necks 16 and 36 abut the stops 114a and 214a of the holders 206 and 306, the first and second vessels 10 and 30 are rotated to engage the protrusions 20c (only the protrusions 20c of the first vessel 10 are shown in the drawings) provided on the outer surfaces of the necks 16 and 36 with the lugs 116 and 216. This secures the first and second vessels 10 and 30 to the holders 106 and 206 of the first and second openers 100 and 200.

After the first and second vessels 10 and 30 are mounted to the first and second openers 100 and 200, the

contents of the first and second vessels 10 and 20 are removed. In the following description, the operation of removing the solid medicament contained within the first vessel will be described.

5 The mechanism 120 may be activated by an operator so that the nut 128, the connection member 140 and the holder 106 with the first vessel 10 secured to the holder 106 move downwardly. When the tips 156c of the cutting edge 156a of the cutter 150 contact the membrane 24
10 closing the opening 18 of the first vessel 10, the cutter 150 initiates cutting the membrane 24 in the opposite direction along the inner periphery of the opening 18 of the neck 16. Penetration of the inclined end 156 into the membrane 24 proceeds the cutting operation so that
15 the membrane 24 is cut along the inner periphery of the opening 18, except for a portion which is located corresponding to the location of the slit 158. The serrated portion 156b aids the cutting performance when the cutting operation is advanced and the tension in the
20 membrane is reduced.

 Then, the mechanism 120 moves the nut 128, the connection member 140, the holder 106 and the holder 106 upwardly from the cutter 150. Moving the vessel 10 from the cutter 150 makes the solid medicament within the
25 first vessel 10 to fall down onto the receiving member 170. At this time, the portion of the membrane 24 which has not been cut by the cutter 150 due to the slit 158 keeps the membrane 24 connected to the neck 16. The water is directed to the solid medicament on the
30 receiving member 170 through nozzle 180 to dissolve the solid medicament into the sprayed water. The solution flows back to the tank 302 through the outlet 105a and the conduit 312. The tank 302 must have a volume at least the volume of the first opener 100 to receive all
35 of the solution at once.

 After the solid medicament is completely solved, the water supply through the nozzle 180 is ended and the

washing nozzles 182 and 184 start to spray water to clean the inside of the housing 102, 104 and 105 and the cutter 150. In particular, the openings 152a of the cutter 150 allow the sprayed water to access the inside of the hollow cutter 150 sufficiently.

The second opener 200 functions substantially the same as the first opener 100 except that, while the first vessel 10 contains a solid medicament, the second vessel 30 mounted to the second opener 200 contains a liquid medicament so that the dissolving operation of the content of the vessel is not required. Thus, unsealing the membrane attached to the opening of the second vessel 30 removes the liquid medicament from the second vessel 30 so that the liquid medicament flows to the tank 302 through the outlet 204a of the second opener 200 without any operation. After completion of the evacuation of the second vessel 30, the water supplying nozzle 262 sprays water toward the inside of the second vessel through the central bore of the cutter 250 to clean the insides of housing 202 and 204, the vessel 30 and the cutter 250.

With reference to Figure 10, an opener according to another embodiment of the invention will be described below.

The opener 400 includes a housing 402 and a holder 404 to which the vessel 10 is mounted, same as the above-described embodiment. Although it is not shown in Figure 10, the opener 400 also includes a mechanism, substantially the same as the mechanisms 120 and 240.

The holder 404 includes a first plain gear wheel 406 attached to the top of the holder 404. The first gear wheel 406 engages a drive gear wheel 408 attached to a shaft of an electric motor 410. The electric motor 410 is securely mounted to a frame 430. The rotation of the drive gear wheel 408 rotates the holder 404 through the engagement between the drive gear wheel 408 and the first gear wheel 406.

The drive gear wheel 408 also engages a second plain gear wheel 412. The second plain gear wheel 412 is

connected to a bevel gear 414 by a shaft 416 to rotate therewith. The bevel gear 414 engages a second bevel gear 418. A pinion gear 420 is coaxially connected to the second bevel gear 418 to rotate therewith. The
5 pinion gear 420 engages a rack 422 provided on a drive bar 424 which has a stop ring 424a at the end opposite to the rack 422.

Provided beneath the drive bar 424 is a driven bar 426 which horizontally extends through the housing 402.
10 The driven bar 426 is displaceably supported by a bracket 432 at one end, and the housing 492 at the other end. The bracket 432 is connected to the frame 430. A piece 428 is secured to the driven bar 428 to move therewith. The piece 428 has an aperture (not shown in
15 Figure 10) through which the drive bar 424 extends. Provided on the drive bar between the stop ring 424a and the piece 428 is a coil spring 434. Likewise, a coil spring 436 is provided on the driven bar 426 between the piece 428 and the bracket 432.

20 Provided on the driven bar 426 is a knife 438 which has a cutting edge 438a facing the membrane 24 sealingly closing the opening of the first vessel 10. A receiving member 440 in the form of a basket, which includes a screen or mesh provided in at least the bottom and
25 portion of the side wall, is provided beneath the knife 438. A pair of nozzles 442 is attached to direct water to the solid medicament received by the receiving member 440.

30 The functional operation of the opener 400 will be described below.

The first vessel 10 is mounted to the opener 400, as described above. After the first vessel 10 is mounted to the opener 400, the mechanism, substantially identical to the mechanism 120 and 220, may be activated by an
35 operator to move the holder 404 downwardly with the first vessel 10 secured to the holder 404. The electric motor 410 is activated when the first gear wheel 406 engages

the drive gear wheel 408. The activation of the electric motor 410 rotates the holder 404 through the engagement between the first gear wheel 406 and the drive gear wheel 408. Further, the activation of the electric motor 410 moves the drive bar 424 to the right in Figure 10 through the gear train of the drive gear wheel 408, the second gear wheel 412, shaft 416, bevel gears 414 and 418, the pinion 420 and the rack 422. When the cutting edge 438a of the knife 438 contacts the membrane 24 closing the opening the first vessel 10, the cutting edge 438a of the knife 438 is substantially at the inside of the opening of the first vessel 10. The rotation of the holder 404 with the first vessel 10 secured to the holder 404 cuts the membrane 24 along the inner periphery of the opening of the first vessel 10.

The activation of the electric motor 410 is continued until the membrane 24 is cut along the inner periphery of the opening except for a portion to keep the membrane 24 cut by the knife 438 connected to the neck 16 by the portion.

When the opening of the first vessel 10 is unsealed, the solid medicament within the first vessel 10 falls down into the receiving member 440. The water is directed to the solid medicament in the receiving member 440 through nozzles 442 to solve the solid medicament into the sprayed water. The solution flows back to the tank 302 through the outlet 402a and the conduit 312.

It will also be understood by those skilled in the art that the forgoing description is a preferred embodiment of the disclosed device and that various changes and modifications may be made without departing from the spirit and scope of the invention.

CLAIM

1. An apparatus for preparing a fluid for a medical procedure by mixing of at least one medicament in the form of powder with water, the medicament being held in a vessel which defines a bottom, a side wall, and a top opening which is closed by a membrane for sealing the inside of the vessel; the apparatus comprising:

a source of water;
an opener for opening the membrane of the vessel, the opener including a holder for vertically holding the vessel to downwardly orient the opening;

a cutter, provided beneath the opening of the vessel held by the holder, for partially cutting the membrane along the periphery of the opening;

a mechanism for vertically moving the holder toward the cutter so that the cutting edge of the cutter pierces and partially separates the membrane from the periphery of the opening whereby the medicament in the vessel falls from the vessel;

a receiving member, in the form of a mesh provided beneath the cutter, for receiving all of the medicament from the vessel; and

a nozzle for directing water from the source of water in the form of a spray to the medicament received by the receiving member to dissolve the medicament into the water directed to the medicament; and

a tank for receiving and containing the substances dissolved in the sprayed water.

2. An apparatus according to claim 1, wherein the tank is adapted to receive the water from the water source; and

the apparatus further comprising a circulating system for supplying the water from the tank to the nozzle.

3. An apparatus according to claim 1 wherein the opener further comprises a housing for enclosing the cutter and the receiving member, the holder being vertically displaceable relative to the housing, and the
5 nozzle is attached to the housing to direct the water to the medicament received by the receiving member from outside of the housing.

4. An apparatus according to claim 1 wherein the
10 mesh size of the receiving member is of at least 20 μm , preferably 50 - 150 μm .

5. An apparatus according to claim 1, wherein the mechanism comprises a feed screw vertically supported for
15 rotation;

a motor, connected to one end of the feed screw, for rotating the screw;

a nut engaging the feed screw; and

a member connected between the nut and the
20 holder.

6. An apparatus according to claim 1, wherein the cutting edge includes a serrated portion provided along the inclined end.
25

7. An apparatus according to claim 6, wherein the serrated portion is partially provided along the inclined end of the cutter body.

8. An apparatus according to claim 7, wherein the serrated portion is disposed on the proximal half of the inclined end.
30

9. An apparatus according to claim 6, wherein the serrated portion is provided all around the inclined end of the cutter body.
35

10. An opener for opening the membrane of a vessel which contains at least one medicament in the form of powder and defines a bottom, a side wall, and a top opening which is closed by an membrane for sealing the inside of the vessel after the vessel receives a predetermined amount of the medicament, the opener comprising:

a holder for vertically holding the vessel to downwardly orient the opening;

a cutter, provided beneath the opening of the vessel held by the holder, for partially cutting the membrane along the periphery of the opening;

a mechanism for vertically moving the holder toward the cutter so that the cutting edge of the cutter pierces and partially separates the membrane from the periphery of the opening whereby the medicament in the vessel falls from the vessel;

a receiving member, in the form of a mesh provided beneath the cutter, for receiving all amount of the medicament from the vessel; and

a nozzle for directing water in the form of a spray to the medicament received by the receiver member to dissolve the medicament into the water directed to the medicament.

11. An opener according to claim 10 further comprising a housing for enclosing the cutter and the receiving member, the holder being vertically displaceable relative to the housing, and the nozzle being attached to the housing to direct the water to the medicament received by the receiving member from outside of the housing.

12. An apparatus according to claim 10 wherein the mesh size of the receiving member is of at least 20 μm ,

preferably 50 - 150 μm .

13. An opener according to claim 10, wherein the
mechanism comprises a feed screw vertically supported for
rotation;

a motor, connected to one end of the feed
screw, for rotating the screw;

a nut engaging the feed screw; and

a member connected between the nut and the
holder.

14. A cutter for partially cutting a membrane along
a periphery of an opening of a vessel which contains at
least one medicament in the form of powder and defines a
bottom, a side wall, and a top opening which is closed by
an membrane for sealing the inside of the vessel after
the vessel receives a predetermined amount of the
medicament, the cutter comprising:

a cutter body substantially in the form of
a hollow cylinder having an inclined end;

a cutting edge provided along the inclined
end;

a slit extending from the inclined end
into the cutter body.

15. A cutter according to claim 14, wherein the
cutting edge includes a serrated portion provided along
the inclined end.

16. A cutter according to claim 15, wherein the
serrated portion is partially provided along the inclined
end of the cutter body.

17. A cutter according to claim 16, wherein the
serrated portion is disposed on the proximal half of the
inclined end.

18. A cutter according to claim 15, wherein the serrated portion is provided all around the inclined end of the cutter body.

5 19. An apparatus for preparing a fluid for a medical procedure by mixing of first and second medicaments with water, the first and second medicaments being held in first and second vessels each of which defines a bottom, a side wall, and a top opening which is
10 closed by an membrane for sealing the inside of the vessel; the apparatus comprising:

 a source of water;

 a first opener for opening the membrane of the first vessel, the first opener including a holder for
15 vertically holding the first vessel to downwardly orient the opening;

 a cutter, provided beneath the opening of the first vessel held by the holder, for partially cutting the membrane along the periphery of the opening;

20 a mechanism for vertically moving the holder toward the cutter so that the cutting edge of the cutter pierces and partially separates the membrane from the periphery of the opening whereby the medicament in the vessel falls from the vessel;

25 a receiving member, in the form of a mesh provided beneath the cutter, for receiving all amount of the medicament from the first vessel; and

 a nozzle for directing water from the source of water in the form of a spray to the first
30 medicament received by the receiving member to dissolve the first medicament into the water directed to the medicament;

 a second opener for opening the membrane of the second vessel, the first opener including a holder
35 for vertically holding the second vessel to downwardly orient the opening;

 a cutter, provided beneath the opening of

the second vessel held by the holder, for partially cutting the membrane along the periphery of the opening;

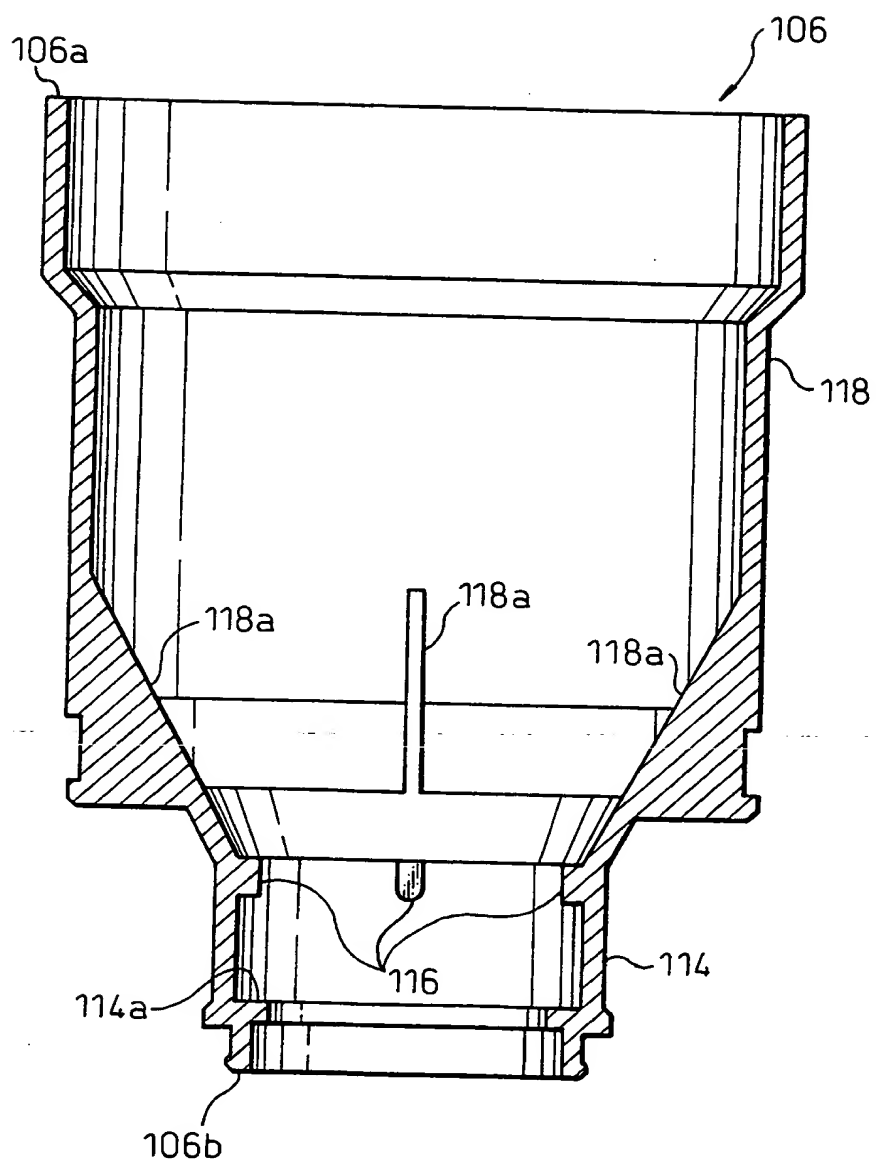
5 a mechanism for vertically moving the holder toward the cutter so that the cutting edge of the cutter pierces and partially separates the membrane from the periphery of the opening whereby the second medicament in the vessel falls from the vessel; and

10 a nozzle for directing water from the source of water in the form of a spray to the inside of the second vessel; and

a tank for receiving and containing the substances dissolved into the sprayed water.

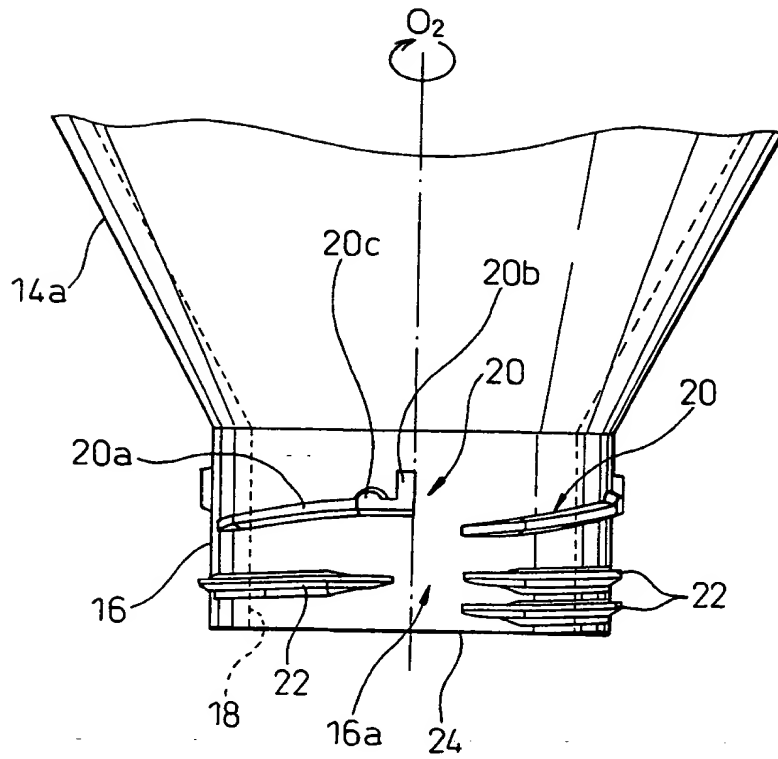
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Fig.3



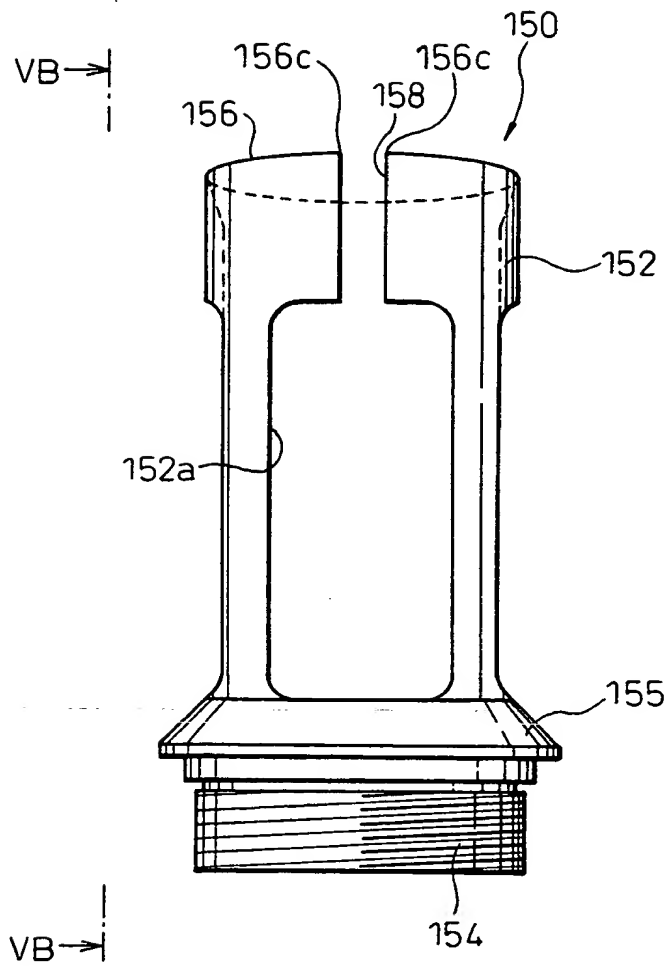
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Fig.4



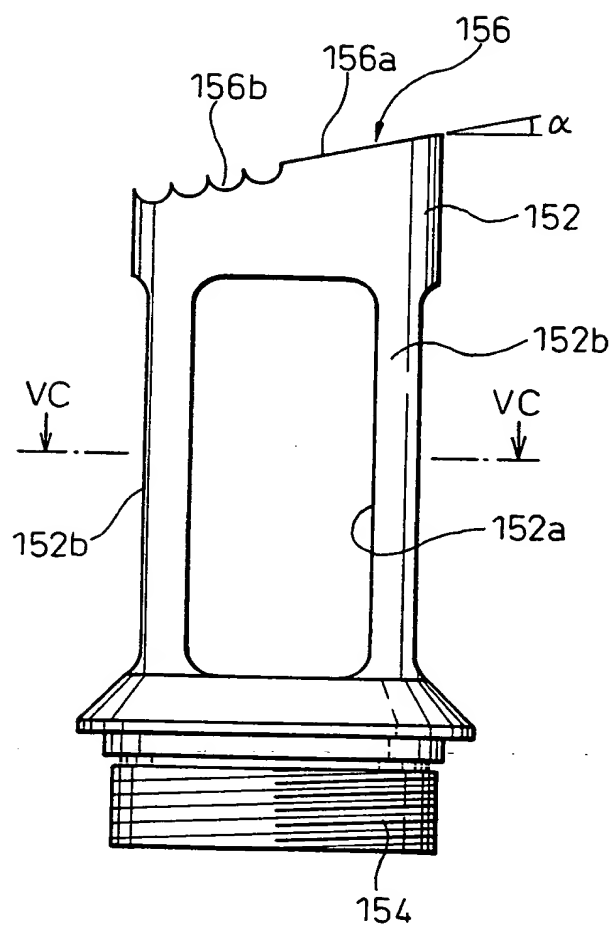
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Fig. 5A



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Fig. 5B



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Fig. 5C

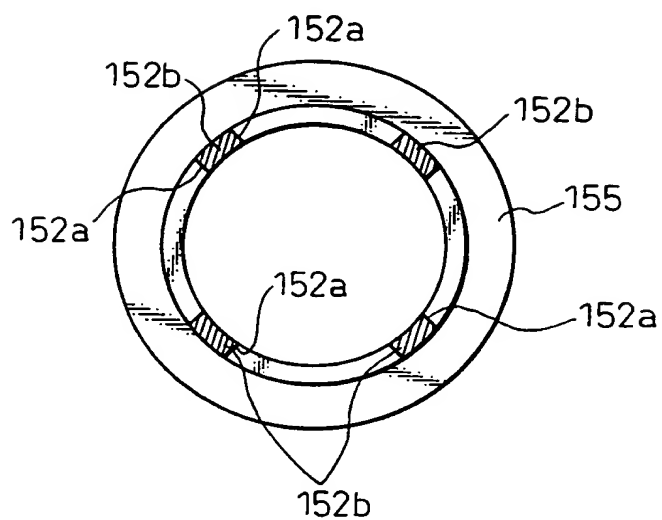


Fig. 5D

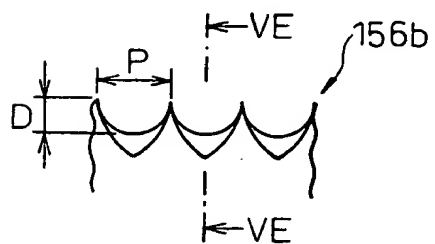
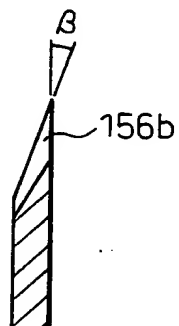


Fig. 5E



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Fig.6

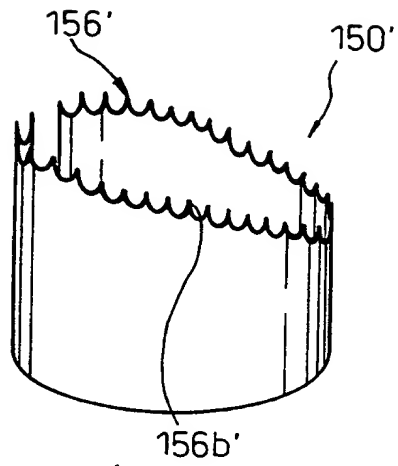
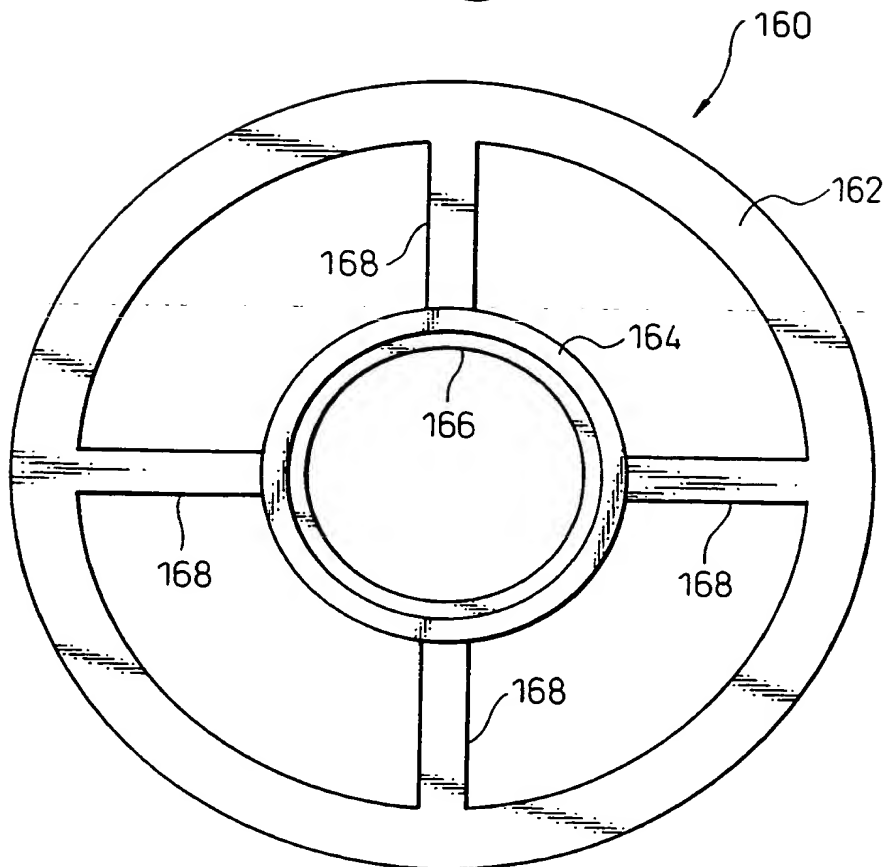
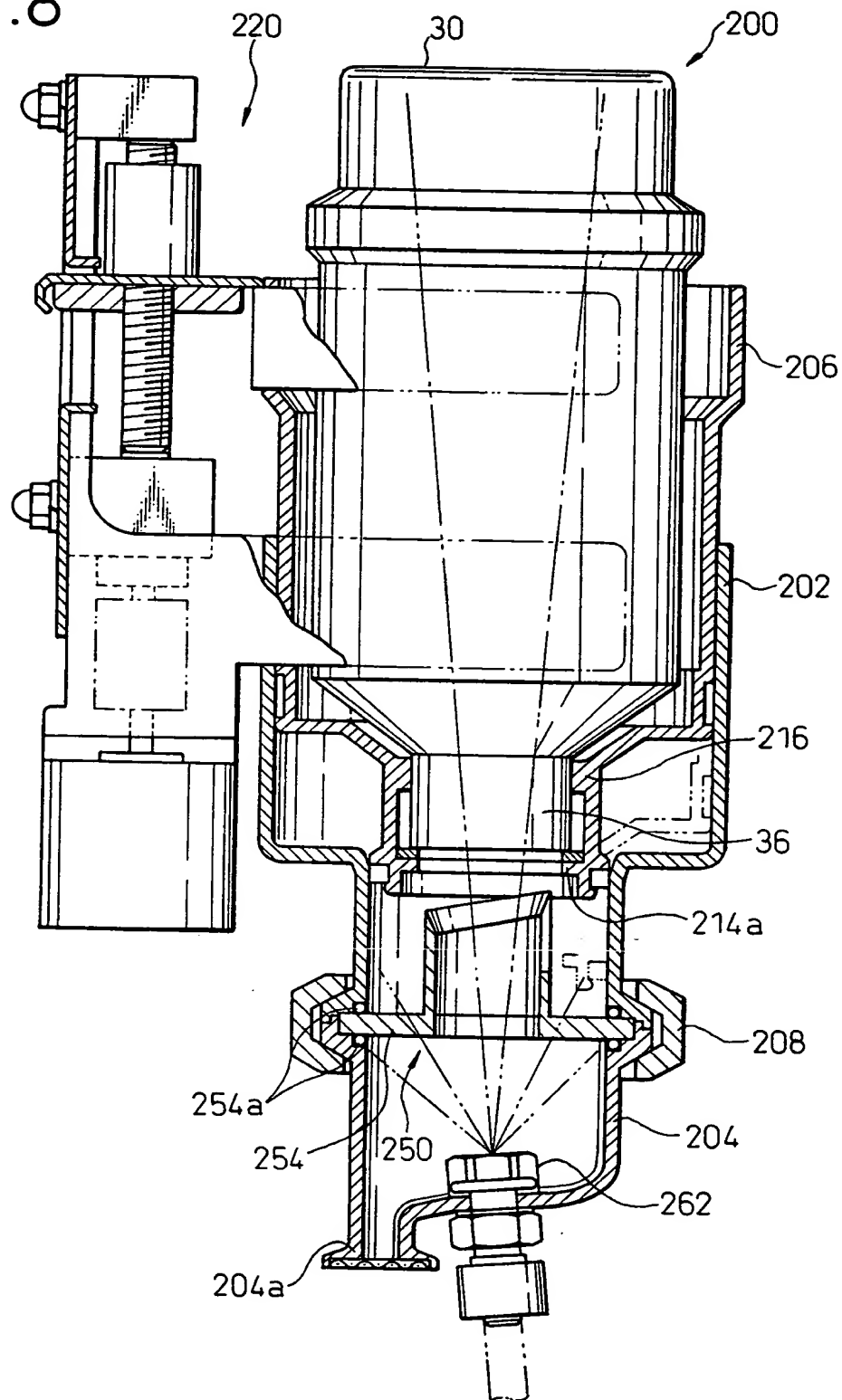


Fig.7



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Fig.8



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Fig.9A

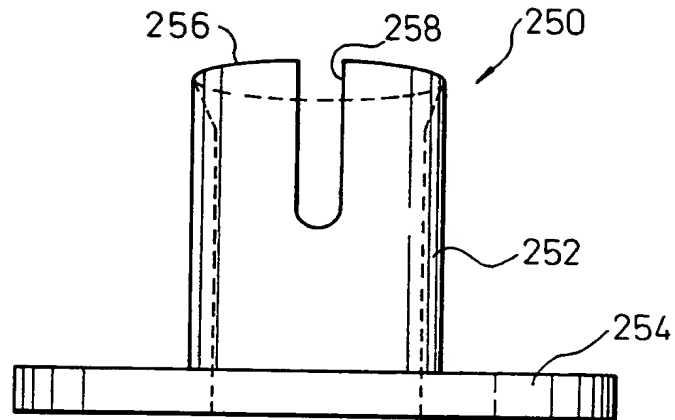
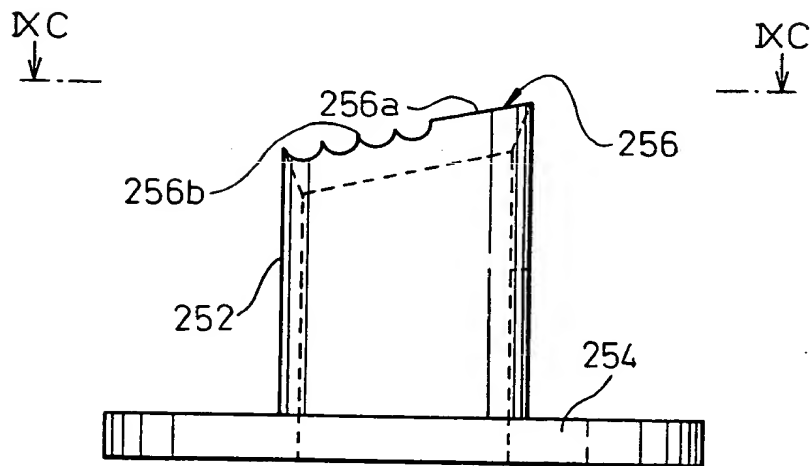
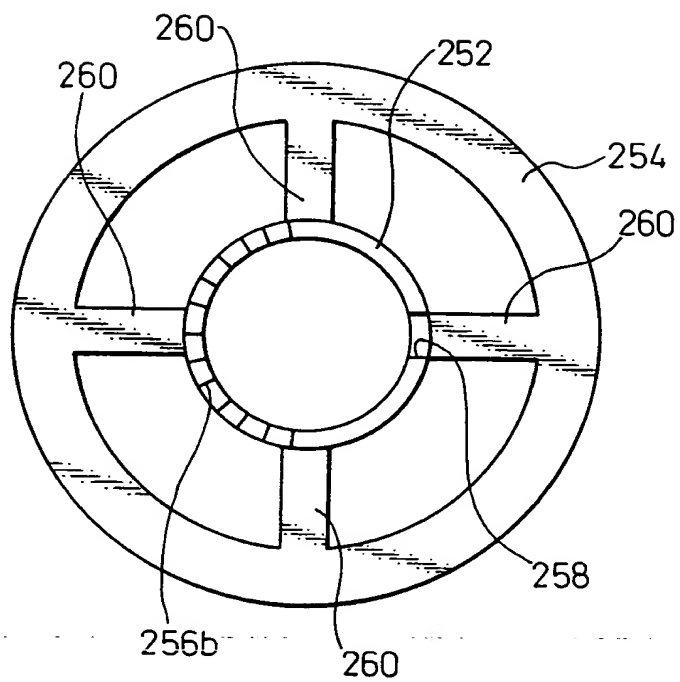


Fig.9B



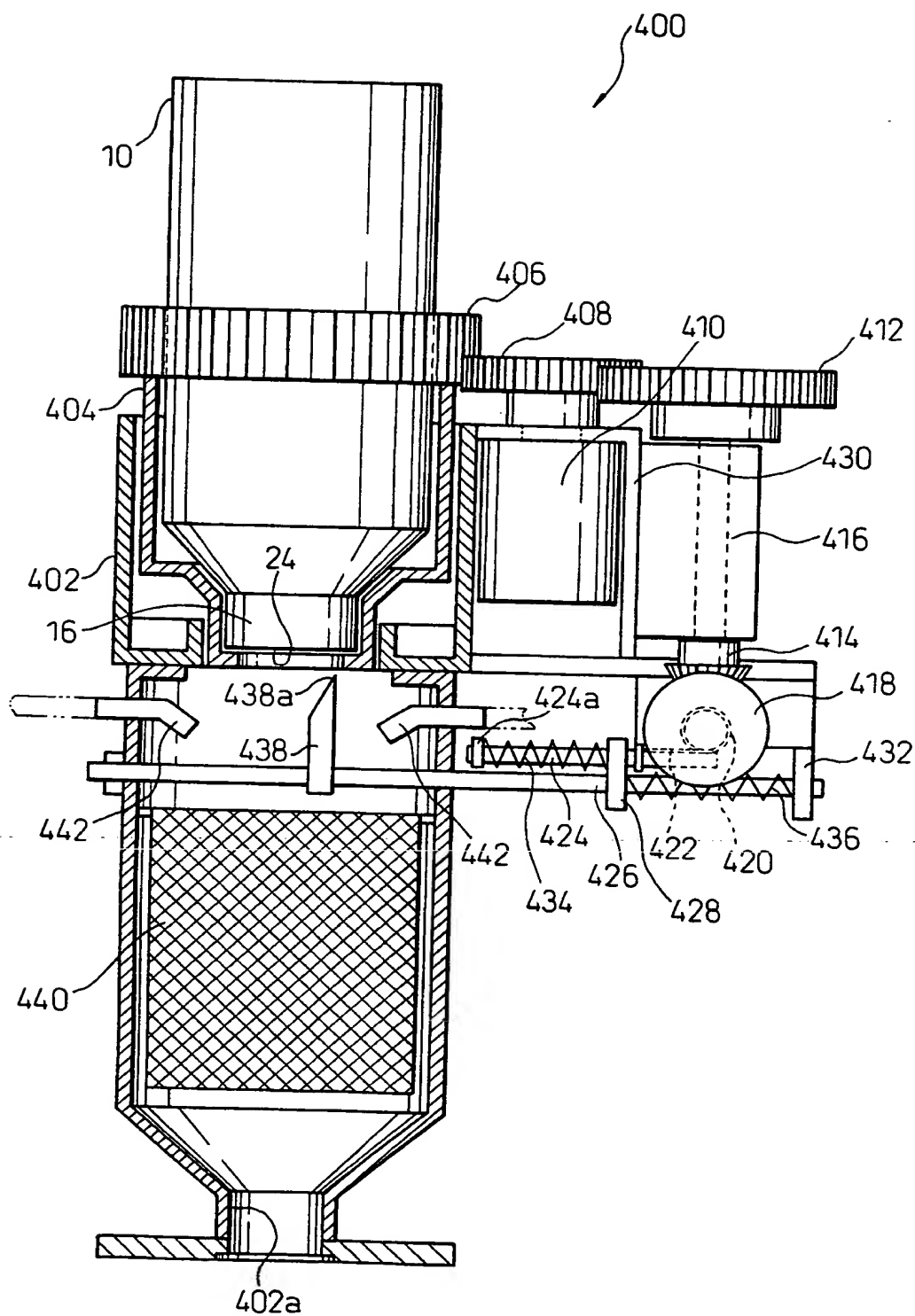
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Fig.9C



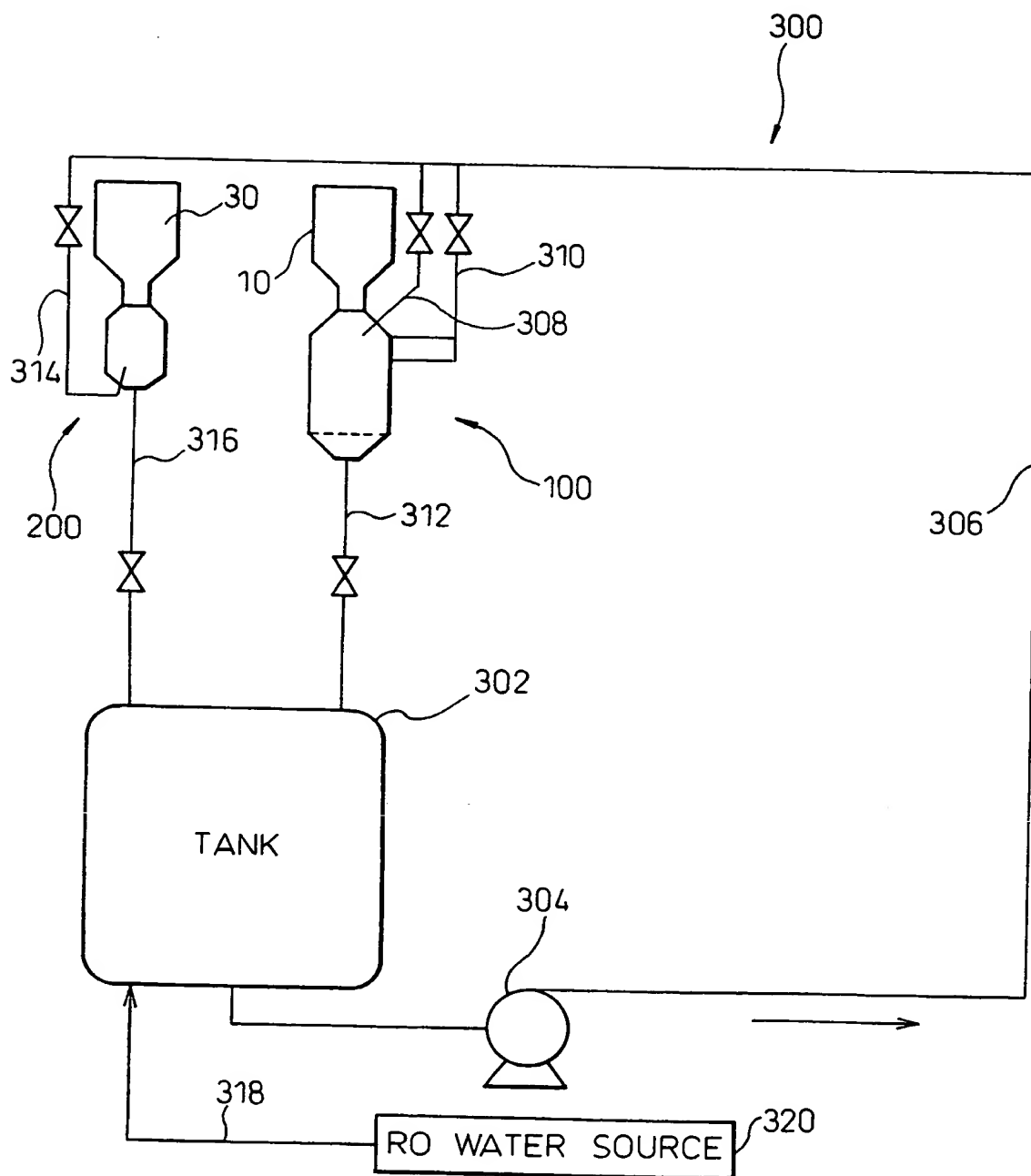
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Fig.10



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Fig.11



INTERNATIONAL SEARCH REPORT

Int'l Application No.

PCT/JP 99/07165

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61J B67B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 788 099 A (TREU ET AL.) 4 August 1998 (1998-08-04) column 4, line 7 -column 6, line 37 figures 1-5	1-3,5, 10,11, 13,14,19
Y		6-9, 15-18
X	US 4 197 942 A (GACKI ET AL.) 15 April 1980 (1980-04-15) figures 1B,3A,4A,4B column 10, line 35 -column 11, line 15	14 1,10,19
A		
Y	US 5 366 114 A (BERNSTEIN ET AL.) 22 November 1994 (1994-11-22) abstract figures 2-5	6-9, 15-18

☐ Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "O" document referring to an oral disclosure, use, exhibition or other means
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- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- "S" document member of the same patent family

Date of the actual completion of the international search

30 March 2000

Date of mailing of the international search report

06/04/2000

Name and mailing address of the ISA

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Authorized officer

Schönleben, J

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP 99/07165

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/ JP 99 /07165

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple(groups of) inventions in this international application, as follows:

1. Claims: 1-13,19
Apparatus for preparing a fluid for medical procedure
2. Claims: 14-18
Cutter for partially cutting a membrane along a periphery of an opening of a vessel

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/JP 99/07165

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